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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,523	04/17/2001	Yong-Qian Wu	23754X	5679

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LYON & LYON - GUILFORD PHARMACEUTICALS INC.  
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LOS ANGELES, CA 90071-2066

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/26/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/835,523

Applicant(s)

WU ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-12, 14-22, 24-32, and 34-43 is/are rejected.
- 7) ☒ Claim(s) 3, 13, 23, and 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

As per applicant's request, the restriction has been revised to three groups as set forth in applicant's response. Applicant's election of group I (claims 1-43 (in part) wherein n is 1) in paper no. 10 is acknowledged. The traversal is on the ground of "no serious burden of searching", and the invention is drawn to the subject matter of "N-substituted cyclic aza compounds". Said traversal is not found persuasive because the invention is drawn to four distinct formulae. Each formula is drawn to three different ring systems (pyrazolidine, perhydropyridazine, and hexahydrodiazapine). Thus, there are at least twelve different Markush groups which require separate searches. Therefore, a serious burden of searching exists. By agreeing to revise the restriction according to applicant's request, the examiner has already taken on a fair amount of searching.

The requirement is still deemed proper and is therefore made FINAL.

### *Specification*

The disclosure is objected to because of the following informalities: Several compounds on pages 57-59 are named as "...pyrazinecarboxylate" which is inconsistent with the formula when n equals 1. Note, "pyrazine" is a 1,4-diazine (i.e., a six membered with 2 nitrogens at the 1<sup>st</sup> and 4<sup>th</sup> positions), which is not the ring system in the formulae.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 2, 4-12, 14-22, 24-32, and 34-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Independent claims 1, 4, 7, 11, 14, 17, 21, 24, 27, 31, 34, 37, and 41-43 recite the phrase "*heterocycle is unsubstituted **on** substituted*" (in the definition of R<sub>2</sub>) which has a typographical error. It is believed that the word 'or' is meant in place of 'on'.
- b. Independent claims 1, 4, 7, 11, 14, 17, 21, 24, 27, 31, 34, 37, and 41-43 recite the definition of R<sub>1</sub> to include COOH, COOR<sub>3</sub>, COR<sub>3</sub>, which have double inclusions when R<sub>3</sub> is hydrogen, hydroxy, or alkoxy.
- c. Claims 2, 5, 6, 8-10, 12, 15, 16, 18-20, 22, 25, 26, 28-30, 32, 35, 36, and 38-40 are rejected as being dependent on the independent claims.
- d. Claim 41 recites two different definitions for X. On the one hand, X is a variable on formula I. On the other hand, X is a halide in a reagent. Applicant is requested to resolve the inconsistency.
- e. Claims 41-43 recite processes for making formulae I, II, and IV with R<sub>1</sub> as an array of substituents. However, the starting materials appear to have R<sub>1</sub> as a ketone or

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ester groups. Thus, it is unclear how the other functional groups defined for  $R_1$  can be prepared from said starting materials.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by **Kobayashi et. al.** (EP 104,484). On page 18, Kobayashi et. al. disclose three compounds (39-41) that are embraced by an ester of the instant formula IV with  $n$  as 1, and the following substituents:

- i.  $R_1$  is  $\text{COOR}_3$  (wherein  $R_3$  is  $\text{C}_1\text{-C}_9$  alkyl); or  $\text{COR}_3$  (wherein  $R_3$  is  $\text{C}_1\text{-C}_9$  alkoxy);
- ii.  $R_2$  is an aryl substituted with halogens and carboxy.

Thus at the time of the invention, one skilled in the art would have known how to make some compounds claimed herein.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by **Delaszlo** (US 6,069,163). On column 10, Delaszlo discloses compound #3 that is embraced by the instant formula II with n as 1, and the following substituents:

iii.  $R_1$  is  $CON(R_3)_2$ , wherein  $R_3$  is H or  $C_1-C_9$  alkyl substituted with carboxy;

iv.  $R_2$  is an aryl group.

The disclosed compound also has pharmacological activity, and can be incorporated in a pharmaceutical composition. Thus, at the time of the invention, one skilled in the art would have known how to make some compounds of formula II, and their pharmaceutical compositions.

#### *Claim Objections*


4. Claims 3, 13, 23, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior arts of record do not teach species claimed herein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
RICHARD L. RAY  
PRIMARY EXAMINER  
*Mukund Shah*  
**Supervisory Patent Examiner**  
**Art Unit 1624**



T. Truong

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August 23, 2002